

ATTORNEY DOCKET NO. PRES06-00251
U.S. SERIAL NO. 10/080,986
PATENT

REMARKS:

Claims 1-8 are pending in the patent application.

Claim 1 has been amended.

Claims 9-18 have been withdrawn.

Claims 1-3 have been rejected.

Claim 4 has been objected to.

Claims 5-8 have been allowed.

Claims 1-8 remain in the patent application.

Reconsideration of the claims, as amended, is respectfully requested.

CLAIM REJECTIONS – 35 U.S.C. § 102

On Page 2 of the December 1, 2004 Office Action the Examiner rejected Claims 1-2 under 35 U.S.C. § 102(b) as being anticipated by United States Patent Number 5,342,377 to *Lazerson*.

On Pages 2-3 of the December 1, 2004 Office Action the Examiner rejected Claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by United States Patent Number 3,609,864 to *Bassett*.

It is axiomatic that a prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. MPEP § 2131; *See, In re King*, 231 USPQ 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*,

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221 USPQ 481, 485 (Fed. Cir. 1984)); *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 USPQ 619, 621 (Fed. Cir. 1985).

With respect to Claims 1-2, a determination of anticipation in accordance with Section 102 requires that each feature claimed therein be described in sufficient detail in *Lazerson* to enable one of ordinary skill in the art to make and practice the claimed invention. With respect to Claims 1-3, a determination of anticipation in accordance with Section 102 requires that each feature claimed therein be described in sufficient detail in *Bassett* to enable one of ordinary skill in the art to make and practice the claimed invention.

The Applicants hereby incorporate by reference all of their arguments previously made in the Applicants' Amendment Under 37 C.F.R. § 1.111 dated October 4, 2004. The Applicants also make the following arguments:

A. The *Lazerson* Reference

The Applicants respectfully disagree with the Examiner's assertions regarding the subject matter disclosed in the *Lazerson* reference. The Applicants respectfully submit that the *Lazerson* reference does not show each and every limitation of the Applicants' invention. The Applicants direct the Examiner's attention to amended Claim 1, which contains unique and novel limitations:

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1. (Currently amended) A surgical blade for use with a surgical tool for making an incision in scleral tissue of an eye, said surgical blade comprising:
a rotatable support arm having a first end capable of being coupled to a drive shaft of said surgical tool that is capable of rotating said rotatable support arm; and
a curved cutting blade having a first end detachably coupled to a second end of said rotatable support arm, said curved cutting blade having a second end that is capable of being moved in an arcuate path through said scleral tissue of said eye by a rotation of said rotatable support arm of said surgical tool to make an incision having the form of a scleral pocket that is capable of receiving a scleral eye implant prosthesis. (Emphasis added).

The Applicants have amended Claim 1 in order to more clearly claim the Applicants' invention. The rotatable support arm of the surgical tool of the invention moves the second end of the curved cutting blade in an arcuate path through the scleral tissue of the eye. This incision through the scleral tissue of the eye forms a scleral pocket that is capable of receiving a scleral eye implant prosthesis. The phrase "moved in an arcuate path" more clearly describes the action of the curved cutting blade. This amendment is to clarify the wording of the claim. This amendment preserves the scope of the original claim and therefore is not a narrowing amendment.

The rotating blade disclosed by *Lazerson* is not capable of being moved in an arcuate path through the scleral tissue by the rotation of a rotatable support arm to form an incision having the form of a scleral pocket in the manner disclosed and claimed in the present invention. The *Lazerson* reference discloses a simple cutting element 52 for cutting a circular opening in an anterior capsule wall in an eye through which a suction element may be inserted to draw out a cataract from within the capsule of the eye. That is, the *Lazerson* blade is designed to perform a capsulotomy on an eye. A comparison of the *Lazerson* blade with the blade of the Applicants' invention shows that the

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Lazerson blade is not capable of being moved in an arcuate path through the scleral tissue by the rotation of a rotatable support arm in order to form a scleral pocket. The *Lazerson* blade does not move in an arcuate path within the anterior capsule wall 18. Instead, the *Lazerson* blade rotates with respect to axis 70 of the axle 54 so that the *Lazerson* blade can cut along the surface of anterior capsule wall 18 to form a circular path 76 of the type shown in FIGURE 13. The *Lazerson* blade is not capable of forming a scleral pocket in the manner of the Applicants' invention.

The Examiner stated that "Regarding the Applicants' argument that *Lazerson's* blade is incapable of being rotated into eye tissue [page 14, first full paragraph] Examiner disagrees." (December 1, 2004 Office Action, Page 5, Lines 12-13). The Applicants' argument was that "The rotating blade disclosed by *Lazerson* is not capable of being rotated into scleral tissue to form a scleral pocket in the manner disclosed and claimed in the present invention." (Emphasis added) (October 4, 2004 Amendment, Page 14, Lines 3-4). The Applicants point out that in the normal use of the *Lazerson* blade (as described in the *Lazerson* reference) the *Lazerson* blade is not rotated into the scleral tissue. The rotation of the *Lazerson* blade is around the axis 70 of the axle 54. (*Lazerson*, Figure 4, Column 5, Lines 5-6).

The Examiner stated that "Because *Lazerson's* blade/rotatable arm assembly rotates about axis (70), the user could jab the distal tip (68) of the blade [Fig. 4] into tissue and then the user could turn/push drive shaft (30) causing the blade to face resistance from the eye tissue and thus rotate relative to the drive shaft (30). It is therefore *capable* of such an intended use." (Emphasis in

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original) (December 1, 2004 Office Action, Page 5, Lines 13-17). The Applicants respectfully traverse this conclusion of the Examiner for the following reasons.

Even if the *Lazerson* blade were used as the Examiner described, the *Lazerson* blade would still not be able to create an incision in the scleral tissue in the form of a scleral pocket that is capable of receiving a scleral eye implant prosthesis. If the user jabbed the distal tip (68) of the *Lazerson* blade 60 into the scleral tissue, then blade 60 would cut through the scleral tissue and make a straight incision in the scleral tissue. The straight incision in the scleral tissue would not form a scleral pocket.

Further, there would not be sufficient "resistance from the eye tissue" to rotate the blade 60 with respect to the drive shaft 30. The blade 60 would cut directly down into the scleral tissue. Even if there were sufficient "resistance from the eye tissue" to cause the blade 60 to rotate around axis 70 of axle 54, the resulting incision would simply be another straight incision down into the scleral tissue at a angle with respect to the first straight incision. Continued rotation of blade 60 around the axis 70 of axle 54 would create additional straight incisions. None of the incisions created in this manner would form a scleral pocket.

In any event, the *Lazerson* device does not move the second end of the *Lazerson* blade 60 in an arcuate path through the scleral tissue of an eye by a rotation of a rotatable support arm to make an incision having the form of a scleral pocket, as claimed in amended Claim 1. Therefore, the *Lazerson* reference does not anticipate amended Claim 1.

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With respect to unamended Claim 2, it is equally clear that the *Lazerson* blade 60 is not capable of making an "incision" in scleral tissue having the dimensions set forth in Claim 2.

For these reasons, the Applicants submit that the *Lazerson* reference does not anticipate amended Claim 1 and unamended Claim 2 of the patent application. The Applicants respectfully request that the Examiner withdraw the anticipation rejections of amended Claim 1 and unamended Claim 2.

B. The *Bassett* Reference

The Applicants respectfully disagree with the Examiner's assertions regarding the subject matter disclosed in the *Bassett* reference. The Applicants respectfully submit that the *Bassett* reference does not show each and every limitation of the Applicants' invention. The Applicants again direct the Examiner's attention to amended Claim 1, which contains unique and novel limitations.

The Applicants agree that the surgical blade handle disclosed by *Bassett* is rotatable. The Applicants also agree that the *Bassett* blade is capable of cutting scleral tissue. However, the structure of the *Bassett* surgical blade handle is rotatable around the central axis of handle shell 28 and drive shaft 30. The *Bassett* blade can not be rotated down into the surface of the material that it is cutting to form a scleral pocket of the type disclosed and claimed by the Applicants.

The Examiner stated that the *Bassett* cutting blade 24 is "capable of being rotated in any way the user desires, including rotating the blade through body tissue such as scleral tissue."

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(December 1, 2004 Office Action, Page 3, Lines 2-4). The Applicants respectfully traverse this assertion of the Examiner because the *Bassett* cutting blade 24 can not be rotated "in any way the user desires." The *Bassett* cutting blade 24 is restricted to rotation around the central axis of handle shell 28 and drive shaft 30. The axial rotation of the *Bassett* cutting blade 24 is therefore not capable of rotating in a manner that will form a scleral pocket due to the rotation.

Further, the *Bassett* reference teaches the following:

"When the knurled cap 31 is rotated counter-clockwise, the compression force of seat portion 30A is removed from the spherical anchoring end 29 of the blade holder 20, thereby allowing the blade holder 20 to pivot through an arc of at least 180° until the neck 36 of the blade holder comes in contact with the end of the slotted socket 27, as shown in FIG. 3A." (*Bassett*, Column 4, Lines 4-10, Figure 3A). "The surgical blade holders of this invention are capable of positioning the surgical blade with its cutting edge extending at a predetermined angle, which may be adjusted through a range of at least 180°" (Emphasis added) (*Bassett*, Column 1, Lines 56-59).

When the user moves the blade holder 20 to the desired angle, the knurled cap 31 is rotated in a clockwise manner to move the clamping rod 30 to engage the spherical anchoring end 29 to firmly secure the blade holder 20 and supporting blade 24. (*Bassett*, Column 3, Lines 58-70).

From this description it is clear that the "rotation" of the *Bassett* blade holder 20 to a desired angle is accomplished "off line" and before the *Bassett* blade is employed in making an incision. Therefore, the *Bassett* device is not capable of "rotating" the blade 24 during an incision process.

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The incision process must be stopped, the spherical anchoring end 29 must be disengaged, the blade holder 20 moved to a new angle, and the spherical anchoring end 29 must be engaged once more.

It is therefore clear that the *Bassett* cutting blade 24 is not capable of rotating into the scleral tissue while it is cutting the scleral tissue. Therefor the *Bassett* cutting blade 24 is not able to form a scleral pocket of the type disclosed and claimed by the Applicants. In any event, the *Bassett* device does not move the second end of the *Bassett* blade 24 in an arcuate path through the scleral tissue of an eye by a rotation of a rotatable support arm to make an incision having the form of a scleral pocket, as claimed in amended Claim 1. Therefore, the *Bassett* reference does not anticipate amended Claim 1.

With respect to Claim 2, it is equally clear that the *Bassett* cutting blade 24 is not capable of making an "incision" in scleral tissue having the dimensions set forth in Claim 2. The Examiner stated that "The specifications of the cut size are more dependent on the skill of the surgeon than on the mechanical features of the invention." (December 1, 2004 Office Action, Page 3, Lines 7-9). The Applicants respectfully traverse this assertion of the Examiner. The Applicants' device is designed to allow a surgeon to make the very precise incisions that are required to properly form a scleral pocket. (Specification, Page 7, Line 16 to Page 8, Line 16). The *Bassett* cutting blade 24 is not capable rotating to make a scleral pocket having the dimensions set forth in Claim 2.

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Claim 3 is dependent on amended Claim 1. The *Bassett* cutting blade 24 does not have the limitations that are set forth in amended Claim 1. Therefore, the *Bassett* cutting blade 24 does not anticipate amended Claim 1 and also does not anticipate Claim 3.

For these reasons, the Applicants respectfully submit that the *Bassett* reference does not anticipate Claims 1-3, as amended, of the patent application. The Applicants respectfully request that the Examiner withdraw the anticipation rejections of Claims 1-3, as amended.

The Applicants also respectfully request that the Examiner withdraw the objection to Claim 4 for the reasons that have been set forth above.

Claims 5-8 have been allowed. The Applicants acknowledge and accept the allowance of Claims 5-8.

The Applicants respectfully request that Claims 1-4, as amended, also be passed to allowance. The Applicants respectfully deny any position or averment of the Examiner that is not specifically addressed by the foregoing argument and response.

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SUMMARY

If any issue arises, or if the Examiner has any suggestions for expediting allowance of this application, the Applicants respectfully invite the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

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